



## HEALTHPARTNERS INSTITUTE FINANCIAL CONFLICT OF INTEREST (FCOI) STANDARD OPERATING PROCEDURE

<b>Subject</b>	<b>Financial Conflict of Interest</b>	<b>Attachments</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<b>Key Words:</b>	Financial Conflict of Interest; Significant Financial Interest; PHS/NIH Funded Research	<b>Number</b> <b>HPI-BP-2.03</b>
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<b>Manual:</b>	HealthPartners Institute Policy Manual	<b>Last Review Date</b> <b>03/23/2026</b>
<b>Approved By:</b>	Jen Augustson, Vice President, HealthPartners Institute	<b>Next Review Date</b> <b>March 2029</b>
<b>Applicability:</b> This Standard Operating Procedure implements the regulatory requirements provided in 42CFR Part 50 Subpart F for grants and cooperative agreements issued by NIH and applies to the Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by an award or proposal for funding, which may include HealthPartners Institute collaborators or consultants.		<b>Origination Date</b> <b>03/23/2026</b>
		<b>Retired Date</b> <b>NA</b>
<b>Review Responsibility:</b> Director of Research Integrity; HealthPartners Institute Conflict of Interest Committee		

## Introduction

The United States Department of Health and Human Services (HHS) developed the regulations at 42 CFR Part 50 Subpart F, “Promoting Objectivity in Research” to promote objectivity in Public Health Service (PHS) funded research for grants and cooperative agreements. The regulations were first published in 1995 and revised in 2011. This Standard Operating Procedure (SOP) implements the requirements of the 2011 revised Financial Conflict of Interest (FCOI) regulation for grants and cooperative agreements.

The regulations apply to all National Institutes of Health (NIH) grants and cooperative agreements, excluding the Phase 1 Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) applications and awards.

The implementation of the regulation, through the issuance of this Standard Operating Procedure (SOP), establishes procedures that provide a reasonable expectation that the design, conduct and reporting of PHS/NIH-funded research will be protected from bias resulting from an investigator’s financial conflict of interest (FCOI). This SOP also serves to protect the safety of research participants, the reputation of HealthPartners Institute, and of its investigators who participate in PHS/NIH-funded research. These requirements also work together to preserve the public’s trust that the research supported by PHS/NIH is conducted without bias and adheres to the highest scientific and ethical standards.

## Scope and Applicability

This SOP implements the regulatory requirements provided in 42 CFR Part 50 Subpart F for grants and cooperative agreements issued by the NIH and applies to individuals who meet the regulatory definition of “Investigator” (as defined below) and who participate in, or are planning to participate in, NIH-funded research.

## Definitions

For the purpose of this SOP, the following definitions apply:

- **Designated Officials (DOs):** The individuals designated by HealthPartners Institute as Officers to oversee the financial conflicts of interest process, including solicitation and review of disclosures of significant financial interests, identification of FCOIs per the regulatory criteria provided in 42 CFR 50.604(f), and monitoring staff FCOI training requirements. At HealthPartners Institute, the Designated Officials are the President and Chief Science Officer, and the Director of Research Integrity.
- **Financial Conflict of Interest (FCOI):** A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- **Financial Interest:** Anything of monetary value, whether or not the value is readily ascertainable.
- **Institution:** Domestic or foreign, public or private, entity or organization (excluding a federal agency) that is applying for, or that receives, Public Health Service funding.

## HealthPartners Institute Financial Conflict of Interest Standard Operating Procedure

- **Institutional Responsibilities:** Professional activities an investigator performs on behalf of HealthPartners Institute (e.g., research, publication, research consultation, administration, committee memberships, or any other duties defined by their role at the Institute).
- **Investigator:** The Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by an award or proposal for funding, which may include collaborators or consultants. HealthPartners Institute will consider the individual's role, rather than their title, and the degree of independence with which the individual works when determining who is responsible for the design, conduct, or reporting of the PHS-funded research.
- **NIH:** The biomedical research agency of the Public Health Service (PHS).
- **PHS:** The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
- **PHS-Funded Research:** Any activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority.
- **Research:** A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social science research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). As used in the regulation, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project or research resources award.
- **Senior/Key Personnel:** The Project Director or Principal Investigator and any other person identified as senior/key personnel by HealthPartners Institute in the grant application, progress report, or any other report submitted to the PHS/NIH by HealthPartners Institute.
- **Significant Financial Interest (SFI):**
  1. **A domestic or foreign financial interest** consisting of one or more of the following interests of the investigator (and those of the investigator's spouse or dependent children) that reasonably appear to be related to the investigator's institutional responsibilities (e.g., research, consulting, etc.) performed on behalf of HealthPartners Institute:
    - i. **Publicly Traded Entity:** A significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other

## HealthPartners Institute Financial Conflict of Interest Standard Operating Procedure

reasonable measures of fair market value.

- ii. **Non-Publicly Traded Entity:** A significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator (or the investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).
  - iii. **Intellectual Property Rights and Interests:** A significant financial interest exists upon receipt of income greater than \$5,000 received over the preceding 12 months that is related to such rights and interests, e.g., patents, copyrights.
2. Investigators must disclose the occurrence of any reimbursed or sponsored travel that exceeds \$5,000 and is related to the investigator's institutional responsibilities. The initial disclosure of reimbursed or sponsored travel should include income received over the previous twelve months. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The disclosure requirement does not apply to travel reimbursed or sponsored by the following:
    - i. A federal, state, or local government agency located in the United States,
    - ii. A United States institution of higher education,
    - iii. An academic teaching hospital,
    - iv. A medical center, or
    - v. A research institute affiliated with a United States institution of higher education.
  3. The term "significant financial interest" does **not** include, and therefore investigators are not required to disclose, the following types of financial interests:
    - i. Salary, royalties, or other remuneration paid by HealthPartners Institute to the investigator if the investigator is currently employed by HealthPartners Institute, including intellectual property rights assigned to HealthPartners Institute and agreements to share in royalties related to such rights.
    - ii. Any ownership interest in the institution held by the investigator, if the institution is a commercial or for-profit organization.
    - iii. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles.
    - iv. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located in the United States, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.
    - v. Income from service on advisory committees or review panels for a federal, state, or local government agency located in the United States, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with a U.S. institution of higher education.

**NOTE:** The exclusions listed above do not apply to foreign financial interests. Investigators must disclose all foreign financial interests (including income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher

education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure e.g., income in excess of \$5,000.

## Significant Financial Interest Disclosure Requirements

Investigators will disclose their Significant Financial Interests (SFIs) that are related to their “institutional responsibilities” as defined in this SOP. **The disclosure will not be limited to an investigator’s research responsibilities or their funded research as this is too narrow in scope and not consistent with the 2011 regulation.**

The Investigator SFI Disclosures will be retained by HealthPartners Institute as part of the record maintenance requirements.

Investigators will disclose their SFIs at the following times:

- **At the time of application:** The Principal Investigator and all other individuals who meet the definition of ‘Investigator’ must disclose their SFIs to HealthPartners Institute’s Designated Officials. Any new investigator who, after applying for NIH funding or during the course of the research study, plans to participate in the research must similarly disclose their SFI(s) to the Designated Officials promptly and prior to participation in the project.
- **Annually:** Each investigator participating in research under an NIH award must submit an updated disclosure of SFI at least annually (on or before March 1) during the period of the award. The annual disclosure must include any information not disclosed initially to HealthPartners Institute pursuant to this SOP or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on an NIH-funded project directly as an NIH grantee and/or indirectly through a sub-award) that was transferred from another institution, and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).
- **Ad Hoc Basis-New SFIs During the Award:** Each investigator participating in PHS/NIH-funded research must submit an updated disclosure of SFI within thirty (30) days of discovering or acquiring a new SFI. Investigators must also submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

## Review of Significant Financial Disclosures by HealthPartners Institute Officials

The Designated Officials (DOs) will review the SFI disclosures. The role of the DO is assigned to the President and Chief Science Officer of HealthPartners Institute and the Director of Research Integrity. The DOs will review any SFI identified in a disclosure and compare these interests to each PHS/NIH research application and/or award on which the investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the PHS/NIH-funded research and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research award

## HealthPartners Institute Financial Conflict of Interest Standard Operating Procedure

as described below in “Guidelines for Determining Relatedness of Significant Financial Interest to PHS/NIH-Funded Research”.

The SFI disclosures will be reviewed as described below:

- **Prior to the expenditure of awarded funds (e.g., during the Just-in-Time stage):** The Designated Official(s) will review the investigator’s SFI(s) prior to the NIH issuing a new award. If an FCOI is identified, HealthPartners Institute will submit a FCOI report to NIH via the eRA Commons FCOI Module prior to the expenditure of funds under the new award.
- **Annual Disclosure:** The annual disclosure will require the investigator to disclose updated values of any previously disclosed SFIs. The Designated Official(s) will review the investigator’s annual disclosure and use the updated information to determine if any changes are needed to an existing management plan. Any changes to the existing management plan will be reported to NIH when the next FCOI report is due.
- **Ad Hoc Basis – New SFIs During Award Period:** Whenever, in the course of an ongoing NIH-funded research study, an investigator who is new to participating in the research project discloses a SFI or an existing investigator discloses a new SFI, the Designated Official(s) will, within 60 days, review the disclosure of SFI, determine whether the SFI is related to the NIH-funded research, determine whether an FCOI exists, and, if so, implement, on at least an interim basis, a management plan that will specify the actions that have been and will be taken to manage the FCOI.

## Guidelines for Determining Relatedness of Significant Financial Interest to PHS/NIH-Funded Research

The Designated Official(s) will determine whether an investigator’s SFI is related to the research under an NIH award and, if so, whether the SFI is a financial conflict of interest.

- **Relatedness Test:** An investigator’s SFI is related to the research when the Designated Official(s) reasonably determine the SFI:
  - 1) Could be affected by the PHS/NIH-funded research; or
  - 2) Is in an entity whose financial interest could be affected by the PHS/NIH- funded

**Investigator Involvement:** The designated official(s) may involve the investigator in determining whether an SFI is related to the NIH-funded research.

- **FCOI Determination:** A financial conflict of interest exists when the Designated Official(s) reasonably determine that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research. “Significantly” means that that the financial interest would have a material effect on the research.

## Management of Significant Financial Interests that Pose a Financial Conflict of Interest

If a financial conflict of interest exists, the Designated Official(s), in conjunction with the HealthPartners Institute Conflict of Interest Committee, will determine what management conditions and/or strategies will be put into place to manage the FCOI. Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to research personnel working on the study, and/or to the HealthPartners Institute Institutional Review Board, Institutional Animal Care and Use Committee, or Data Safety and Monitoring Board, etc.).
- For research studies involving human subjects, disclosure of financial conflicts of interest directly to participants in the informed consent document.
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest.
- Modification of the research plan.
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
- Reduction or elimination of financial interest (e.g., sale of equity interest)
- Severance of relationships that create financial conflicts.

If the Designated Official(s) determine that a conflict exists, this determination, and the means developed for managing the FCOI will be communicated to the investigator in writing.

No expenditure on an NIH award will be permitted until the investigator has complied with the disclosure requirements of this SOP and has agreed, in writing, to comply with any plans determined by the Designated Official(s) and the HealthPartners Institute Conflict of Interest Committee necessary to manage the Financial Conflict of Interest. The FCOI Designated Official(s) of HealthPartners Institute will submit the FCOI report to NIH via the eRA Commons FCOI Module.

## Monitoring Investigator Compliance

HealthPartners Institute will monitor investigator compliance with the management plan for the duration of the NIH award or until the FCOI no longer exists. Monitoring of public disclosure requirements will include reviewing publications and presentations to confirm that the investigator disclosed the FCOI in such communications. For studies involving human participants, post-approval

monitoring of the study procedures, including the informed consent process and documents may also occur.

## Public Accessibility of Financial Conflict of Interest SOP and Financial Conflict of Interest Information Held by Senior/Key Personnel

**Public Accessibility of FCOI SOP:** To ensure public accessibility, a copy of this FCOI SOP is posted on HealthPartners Institute public website ([Collaborate with HealthPartners Institute](#)) per the NIH requirements in the NIH Grants Policy Statement Section 4.1.10 Financial Conflict of Interest at: [https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_4/4.1.10\\_financial\\_conflict\\_of\\_interest.htm](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.10_financial_conflict_of_interest.htm)

**Identified FCOIs Held by Senior/Key Personnel:** Prior to the expenditure of any funds under an NIH award, HealthPartners Institute will ensure public accessibility by providing a written response to any requestor within five business days of a request for information concerning any SFI disclosed that meets the following three criteria:

1. The SFI was disclosed and is still held by the senior/key personnel,
2. HealthPartners Institute has determined that the SFI is related to the research funded through an award, and
3. HealthPartners Institute has determined that the SFI is a financial conflict of interest.

The information made available via the HealthPartners Institute website or in a written response will include, at a minimum:

1. The Investigator's name
2. The Investigator's title and role with respect to the research study
3. The name of the entity in which the significant financial interest is held
4. The nature of the significant financial interest, and
5. The approximate dollar value of the significant financial interest in the following ranges: \$0-\$4,999; \$5,000- \$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

The written response will note that the information provided is current as of the date of the correspondence and is subject to updates on at least an annual basis and within 60 days of HealthPartners Institute's identification of a new FCOI which should be requested subsequently by the requestor.

HealthPartners Institute may also use its publicly accessible website to meet this requirement and the information posted will be updated at least annually and within 60 days of:

- Receiving or identifying an additional SFI of Senior/Key personnel related to the NIH funded

research that was not previously disclosed, or

- A new SFI being disclosed by Senior/Key personnel joining the study and determined by the designated official(s) to be related to the research and an FCOI.

Information on SFIs subject to the public accessibility requirement will remain available for at least three years from the most recent update.

## Reporting Financial Conflicts of Interest

HealthPartners Institute will assign an institutional official to serve as the FCOI Signing Official (SO) within the eRA Commons FCOI Module. The FCOI SO has the authority to submit FCOI reports to the NIH. FCOI reports are submitted to the NIH only when a grant or cooperative agreement is active and an FCOI is identified. The FCOI Module User Guide is available at [https://www.era.nih.gov/files/fcoi\\_user\\_guide.pdf](https://www.era.nih.gov/files/fcoi_user_guide.pdf) to assist in submitting reports to the NIH.

**The Initial or Original FCOI Report:** The Original FCOI report will include the information required in the regulation at 42 CFR Part 50.605(b)(3) or as outlined in NIH's FAQ H.5 at <https://grants.nih.gov/faqs#/financial-conflict-of-interest>.

- **Prior to the Expenditure of Funds Under a New Award:** When a FCOI is identified upon the issuance of a new NIH award, the FCOI SO will submit an original report prior to the expenditure of any funds under an NIH award.
- **Within 60 Days of Identifying a New FCOI During Award Period:** When a FCOI is identified during the period of an NIH-funded award (e.g., a new SFI is identified for an Investigator, or upon the participation of a new Investigator), HealthPartners Institute will provide to NIH within 60 days of identifying the FCOI, an Original FCOI report regarding the financial conflict of interest.

**Annual FCOI Reports:** While the award is ongoing (including any extensions with or without funds), HealthPartners Institute will provide NIH with an annual FCOI report that addresses the status of the previously reported FCOI and any changes in the management plan, if applicable.

The Annual FCOI report will be submitted at the same time as the Research Performance Progress Report or multi-year progress report is due and at the time of grant extension, if applicable, per NIH guidance (see NIH's FAQ H.2. at <https://grants.nih.gov/faqs#/financialconflict-of-interest>.) NIH will send an annual report email notification to HealthPartners Institute when the annual report is due. Annual FCOI reports are not submitted as part of grant closeout.

**Revision or Mitigation FCOI Reports:** Following the completion of a retrospective review, the HealthPartners Institute will provide NIH with a Revision Report if new information is discovered or a Mitigation Report if bias is found.

## HealthPartners Institute Financial Conflict of Interest Standard Operating Procedure

The types of FCOI reports to be provided to NIH through the eRA Commons FCOI Module and their requirements are summarized below:

<b>Report</b>	<b>Content</b>	<b>When Required</b>
<b>Initial Submission (New FCOI Report)</b>	Grant Number, Principal Investigator Name, Name of Entity with FCOI, Nature of FCOI, Value of Financial Interest (in increments), Description of How Financial Interest Relates to Research, Key Elements of Management Plan.	<ol style="list-style-type: none"> <li>1. Prior to expenditure of funds</li> <li>2. Within 60 days of any subsequently identified FCOI</li> </ol>
<b>Annual FCOI Report</b>	Status of FCOI (still being managed or no longer exists) and any changes to the management plan, if applicable.	Due at the same time as when HealthPartners Institute is required to submit an annual progress report, multi-year progress report, or at the time of extension.
<b>Revised FCOI Report</b>	Updates to a previously submitted FCOI report to describe actions that will be taken to further manage the FCOI or make changes to the originally submitted FCOI report.	Following the completion of a retrospective review when there is noncompliance with the regulation.
<b>Mitigation Report</b>	Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for Review, Details Regarding Methodology, Findings and Conclusion, including what actions have been taken to mitigate the effects of the bias.	When bias is found as a result of a retrospective review.

## Training Requirements

Each Investigator will be informed of this SOP and trained on their responsibility to disclose domestic and foreign SFIs per this SOP and the FCOI regulation at 42 CFR Part 50 Subpart F. FCOI training will

## HealthPartners Institute Financial Conflict of Interest Standard Operating Procedure

occur prior to an Investigator engaging in PHS/NIH-funded research, at least every four years, and immediately when any of the following circumstances apply:

- HealthPartners Institute revises this SOP in any manner that affects the requirements of its investigators.
- An investigator is new to HealthPartners Institute research under an NIH award (training is to be completed prior to their participation in the research).
- HealthPartners Institute finds that an investigator is not in compliance with this SOP or a management plan issued under this SOP (training is to be completed within 30 days in the manner specified by the Designated Officials(s)).

To fulfill the FCOI training requirement, HealthPartners Institute requires its investigators to complete financial conflict of interest training through the CITI program. Additional training resources may also be accessed through the National Institutes of Health' Conflict of Interest Tutorial posted on its website. All investigators are responsible for maintaining their training records for internal monitoring and audit purposes.

## Failure to Comply with HealthPartners Institute Financial Conflict of Interest SOP Applicable to Public Health Service Funded Award

If HealthPartners Institute identifies a SFI that was not disclosed, identified, reviewed or managed in a timely manner, the designated official(s) will within 60 days, review the SFI, determine whether the SFI is related to research, determine whether a FCOI exists, and if so, implement on at least an interim basis a management plan that will specify the actions that have been and/or will be taken to manage the FCOI going forward. The Institution will also submit a FCOI report to PHS/NIH via the eRA Commons FCOI Module.

In addition, when a FCOI is not identified or managed in a timely manner, including:

- Failure by an investigator to disclose a SFI that is determined by HealthPartners Institute to constitute a FCOI.
- Failure by HealthPartners Institute to review or manage a FCOI.
- Failure by the Investigator to comply with a management plan.

HealthPartners Institute will, within 120 days of determining non-compliance:

- Complete a retrospective review of the investigator's activities and the PHS/NIH-funded research study to determine whether any NIH-funded research, or portion thereof, conducted during the period of noncompliance was biased in the design, conduct, or reporting of research.
- Document the retrospective review consistent with the regulation at 42CFR 50.605(a)(3)(ii)(B) or as described in NIH's FAQ I.2 at <https://grants.nih.gov/faqs#/financialconflict-of-interest>.

## HealthPartners Institute Financial Conflict of Interest Standard Operating Procedure

If bias is found, HealthPartners Institute will notify NIH promptly and submit a mitigation report per the regulation at 42 CFR 50.605 (a) (3) (iii) or as described in NIH's FAQ I.3 at <https://grants.nih.gov/faqs#/financialconflict-of-interest> to NIH via the eRA Commons FCOI Module that will address:

- The impact of the bias on the research study, and
- HealthPartners Institute's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, HealthPartners Institute will submit FCOI reports annually to NIH in accordance with the NIH guidance as provided in the summary chart on page 11 of this SOP. Depending on the nature of the FCOI, HealthPartners Institute may determine that additional interim measures are necessary with regard to the investigator's participation in the research study between the date that the FCOI is identified and the completion of HealthPartners Institute's retrospective review.

If bias is not found, no further action will be taken unless new information is discovered that needs to be reported to NIH. If applicable, HealthPartners Institute will update the existing FCOI report to specify the actions that have been or will be taken to manage the FCOI going forward or update previously submitted report information following the completion of the retrospective review.

## Clinical Research Requirements

If the Department of Health and Human Services determines that one of its funded clinical research studies, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an investigator with a FCOI that was not managed or reported by HealthPartners Institute, HealthPartners Institute will require the investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

## Subrecipient Requirements

A subrecipient relationship is established when federal funds flow down from or through HealthPartners Institute to another individual or entity, and the subrecipient will be conducting a substantive portion of a PHS-funded research study and is accountable to HealthPartners Institute for programmatic outcomes and compliance matters. Subrecipients, including but not limited to collaborators, consortium members, consultants, contractors, subcontractors, and sub-awardees, are subject to HealthPartners Institute's terms and conditions. HealthPartners Institute will take reasonable steps to ensure that any subrecipient investigator is in compliance with the federal FCOI regulation at 42 CFR Part 50 Subpart F.

HealthPartners Institute will incorporate, as part of a written agreement with the subrecipient, terms

that establish their FCOI SOP or that of the subrecipient's institution will apply to the subrecipient investigator(s).

- **If the subrecipient's FCOI policy applies:** The subrecipient institution will certify as part of the agreement with HealthPartners Institute that its policy is in compliance with the federal FCOI regulation. The agreement will specify the time period for the subrecipient to report all identified FCOIs to HealthPartners Institute (e.g., within 45 days of identification to allow HealthPartners Institute to report within 60 days) to enable HealthPartners Institute to provide timely FCOI reports to PHS/NIH as required by regulation. The HealthPartners Institute assigned FCOI SO will submit the FCOI report (subrecipient report) to the NIH via the eRA Commons FCOI Module.
- **If the subrecipient cannot provide certification:** The agreement will state that the subrecipient investigator is subject to HealthPartners Institute's FCOI SOP for disclosing SFI(s) that are directly related to the subrecipient's work for HealthPartners Institute. HealthPartners Institute will require the submission of all investigator disclosures of SFIs. The agreement will include sufficient time to allow HealthPartners Institute to comply with its timely review, management, and reporting obligations under the regulation. When a FCOI is identified, HealthPartners Institute will develop a management plan, monitor subrecipient Investigator compliance with the plan, and submit a FCOI report (subrecipient report) to the NIH through the eRA Commons FCOI Module.

## Maintenance of Records

HealthPartners Institute will keep all records of all Investigator disclosures of financial interests and its review of, or response to, such disclosures (whether or not a disclosure resulted in the determination of a FCOI), and all actions under this SOP or retrospective review, if applicable. Records of financial disclosures and any resulting action will be maintained for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 2 C.F.R. 200.334 for different situations. HealthPartners Institute will retain records for each competitive segment as provided in the regulation. Management plans will be retained as part of HealthPartners Institute records.

In addition, HealthPartners Institute will make information available, promptly upon request, to DHHS relating to any investigator disclosure of financial interests and its review of, and response to such disclosure whether or not the disclosure resulted in HealthPartners Institute's determination of a FCOI per the regulation 42CFR 50.606(b).

## Enforcement Actions

Compliance with this SOP is a condition of employment for all applicable investigators. Investigators who fail to comply with this SOP are subject to discipline, including letters of reprimand, restrictions on the use of research funds, disqualification from further participation in any PHS/NIH-funded research, or termination of employment, as deemed appropriate.

## Resources

- NIH's email address to send FCOI-related inquiries: [FCOICompliance@mail.nih.gov](mailto:FCOICompliance@mail.nih.gov)
- FCOI Regulation 42 CFR Part 50 Subpart F: <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>
- Financial Conflict of Interest: <https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi>
- FCOI Training: <https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training>
- FCOI Frequently Asked Questions (FAQs): <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchorff3875>
- Information on Foreign Grants: <https://grants.nih.gov/new-to-nih/information-for/foreign-grants>
- NIH's Welcome Wagon Letter: <https://grants.nih.gov/policy-and-compliance/welcome-wagon>
- NIH Grants Policy Statement: <https://grants.nih.gov/policy/nihgps/index.htm>
- NIH Guide for Grants and Contracts: [NIH Guide for Grants and Contracts | Grants & Funding](#)
- NIH Extramural Nexus: <https://public.govdelivery.com/accounts/USNIHOER/subscriber/new?qspffCODERED>

## Point of Contact

For questions related to this SOP or SFI disclosure, please contact Amy Fehrer, Director of Research Integrity at [Amy.A.Fehrer@HealthPartners.Com](mailto:Amy.A.Fehrer@HealthPartners.Com) or 952-967-5025.